EXHIBIT 2

K121272

Akervall Technologies LLC
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Contact: Stephen Shulman,

OCT 15 2012

July 12, 2012

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: "ProTech Dent,"
   Device Class: Unclassified (Pre Amendment)
   Classification Name: Mouthguard; OBR,
   Common/Usual Name: Mouthguard, Over-the-Counter

2. Equivalent legally marketed devices: OBR : K 072147 DenTek Comfort Fit NightGuard

3. Intended Use: The Akervall Technologies mouthguards (ProTech Dent,) are indicated for use in protecting the teeth and reduce damage caused by bruxism or nighttime grinding.

4. Description of the Devices: Features & Benefits:

The ProTech Dent guard consists of a polycaprolactone based polymer with a tensile strength significantly higher than EVA(29.11 MPa versus 22.3 MPa). It comes in a pre-shaped form (1.6 mm thick). The form softens when heated in hot water and can then easily be custom fit to the user's teeth. When the user sucks on the mouth guard it shapes around the teeth with no or minimal space between the material and the teeth. The polymer hardens in about 30 seconds and is then durable so that it does not deform when impacted with forces typically encountered in the mouth.

5. Technological Characteristics:

The overall shape and dimensions are identical with commercially available mouth guards. They both are composed of a thermoplastic resin. The products are heated in hot water and cooled briefly and then molded to fit the teeth. Thinner than commercially available mouth guards, ProTech Dent is 1.6 mm thick versus 4.0 mm thick for EVA. ProTech Dent is perforated allowing saliva flow, but stronger with regards to impact protection based on laboratory testing (ProTech Dent 29.11 MPA versus EVA 22.3 MPa).

6. Performance Data:
   The physical properties of the ProTech Dent mouthguard were tested and compared to the Den Tek Comfort Fit mouthguard. The hardness properties per the ASTM test showed the Pro Tech Dent shore comparable to the Den Tek Comfort Fit. However, the tensile

strength of the Pro Tech Dent was 3.5 times greater than the Den Tek product. The tensile elongation of the Pro Tech Dent was 1.5 more than the Den Tek product. Also, the Young's Modulus, Water Sorption, Water Solubility, was compared with the predicate device.

Biocompatibility Data: Cytoxicity, Irritation and Sensitization tests were performed on the Pro Tech Dent product.

Design and Use of Device

	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		x
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	x	
Does the device contain components derived from a tissue or other biologic		x
source?		
Is the device provided sterile?		x
Is the device intended for single use?	x	
Is the device a reprocessed single use device?		x
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		x
Does the device contain a biologic?		x
Does the device use software?		x
Does the submission include clinical information?		x
Is the device implanted?		x

5. Comparison to predicate device:

Comparison Areas	DenTek Night Guard K072147	Akervall Technologies ProTech Dent,
Indications for use	Protection against bruxism and grinding. Intended to reduce damage to teeth.	Protection against bruxism and grinding. Intended to reduce damage to teeth.
Design	Adjustable preformed oral device	Adjustable preformed oral
Materials	Thermoplastic resin	Thermoplastic resin
Reusable	Yes, single patient	Yes, single patient

7. Conclusion In all respects, the Akervall Technologies mouth guard is substantially equivalent in terms of design, material, chemical composition and performance to commercially available mouth guards that are legally marketed for this purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 15 2012

Akervall Technologies Incorporated
Ms. Sassa Akervall
President
5520 Stone Valley Drive
Ann Arbor, Michigan 48105

Re: K121272
Trade/Device Name: ProTech Dent
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: September 11, 2012
Received: September 11, 2012

Dear Ms. Akervall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

i) Indications for Use

510(k) Number K122172

Device Name: ProTech Dent,

Indications for Use:

The Akervall Technologies mouthguards (ProTech Dent,) are indicated for use in protecting the teeth and reduce damage caused by bruxism or nighttime grinding.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____OR Over the Counter Use yes
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122172